# COLD AND FLU NIGHTTIME- acetaminophen, dextromethorphan hbr, triprolidine hcl solution WALMART INC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

-----

#### **Equate 44-063**

#### Active ingredients (in each 20 mL)

Acetaminophen 650 mg Dextromethorphan HBr 20 mg Triprolidine HCl 2.5 mg

#### **Purpose**

Pain reliever/fever reducer Cough suppressant Antihistamine

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - headache
  - runny nose
  - sneezing
  - sore throat
  - itching of the nose or throat
  - minor aches and pains
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

## Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

rash

- blisters
- skin reddening

If a skin reaction occurs, stop use and seek medical help right away.

**Sore throat warning:** If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

#### Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

#### Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

### Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

## When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- avoid alcoholic beverages
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

## Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs
  of a serious condition.

## If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

- do not take more than directed
- do not take more than 4 doses in any 24-hour period
- mL = milliliter; FL OZ = fluid ounce
- only use the dose cup provided
- adults and children 12 years and over: 20 mL in dosing cup provided every 4 hours
- children under 12 years: do not use

#### Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

#### Inactive ingredients

anhydrous citric acid, FD&C blue #1, FD&C red #40, FD&C yellow #6, flavors, glycerin, propylene glycol, purified water, sodium benzoate, sucralose, xanthan gum

#### **Ouestions or comments?**

1-888-287-1915

## Principal display panel

## equate<sup>™</sup>

NDC 79903-119-45

Compare to Mucinex® Nightshift® Cold & Flu active ingredients\*

**NIGHTTIME** 

#### Cold & Flu

- Acetaminophen Pain Reliever/Fever Reducer
- Dextromethorphan HBr Cough Suppressant
- Triprolidine HCl Antihistamine

#### Relieves:

- Cough, fever
- Sore throat
- Runny nose, sneezing

Ages 12+

#### 6 FL OZ (177 mL) F-063-45 ORG

#### **PARENTS:**

Learn about teen medicine abuse www.StopMedicineAbuse.org

#### TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

#### **DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716**

\*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Mucinex® NIGHTSHIFT® COLD & FLU. 50844 ORG022206345







#### Drug Facts (continued) Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. if you have ever had an allergic reaction to this product or any of its ingredients if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your before taking this product.



phlegm (mucus)

difficulty in urination due to
enlargement of the prostate gland
a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are ■ taking sedatives or tranquilizers

#### Drug Facts (continued)

- taking the blood thinning drug warfarin
- When using this product

  do not exceed recommended
- dosage

  excitability may occur, especially in children
- avoid alcoholic beverages ■ marked drowsiness may occur ■ alcohol, sedatives, and tranquilizers
- may increase drowsiness use caution when driving a motor
- vehicle or operating machinery Stop use and ask a doctor if

## pain or cough gets worse or lasts more than 7 days

- fever gets worse or lasts more than 3 days ■ new symptoms occur ■ redness or swelling is present
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice a signs or symptoms



Drug Facts (continued)

Inactive ingredients anhydrous citric acid. FD&C blue #1. FD&C red #40, FD&C yellow #6, flavors, glycerin, propylene glycol, purified water, sodium benzoate. sucralose, xanthan gum

Questions or comments? 1-888-287-1915

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716 \*This product is not manufactured oduct is not manufactured led by RB Health (US) LLC, rted by RB Headers of the registered trademark ex® NIGHTSHIFT® COLD & FLU ORG02220634

**Equate 44-063** 

## **COLD AND FLU NIGHTTIME**

acetaminophen, dextromethorphan hbr, triprolidine hcl solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79903-119	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL		
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
XANTHAN GUM (UNII: TTV12P4NEE)				

Product Characteristics				
Color	blue	Score		
Shape		Size		
Flavor	FRUIT	Imprint Code		
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/03/2022	

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	

Category	Citation	Date	Date
OTC monograph final	part341	05/03/2022	

## Labeler - WALMART INC. (051957769)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(79903-119) , pack(79903-119)

Revised: 5/2022 WALMART INC.